Bedfordshire Hospitals NHS Foundation Trust

Bedford Hospital

Inspection report

South Wing
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Ratings

Overall rating for this location	Inspected but not rated
Are services safe?	**Inspected but not rated**
Are services effective?	**Inspected but not rated**
Are services well-led?	**Inspected but not rated**

Our findings

Overall summary of services at Bedford Hospital

Inspected but not rated

Bedford Hospital is operated by Bedfordshire Hospitals NHS Foundation Trust and provides maternity services to women living across the county of Bedfordshire. The maternity unit at Bedford Hospital provides a comprehensive range of inpatient and outpatient services from pregnancy, birth and post-natal care.

The maternity service is managed through the trust's maternity clinical service line. The current leadership structure includes a clinical director, a general manager, an interim director of midwifery and an interim head of midwifery. Obstetricians, matrons, and senior midwives also support the senior leadership team.

The maternity unit is located in the Cygnet wing at Bedford Hospital. The service provides consultant and midwife-led care for both high and low risk women. The consultant-led delivery suite is located on the first floor and has eight delivery rooms, two dedicated obstetric theatres and a two-bedded recovery bay for post-operative women. The Acorn suite is the midwife-led birthing unit and consists of three low-risk birthing rooms and the dedicated bereavement suite called the Butterfly room. The Acorn suite is situated at the far end of the delivery suite.

There is a 24-bedded joint postnatal and antenatal ward, called the Orchard ward located on the second floor of the Cygnet wing. This ward consists of five four-bedded bays and four side rooms, two of which are amenity rooms, which are available to women who wish to pay for a private room. Orchard ward also contains the four-bedded maternity day assessment clinic. The maternity service also has an antenatal outpatient department situated on the first floor of the Cygnet wing. The department includes screening services, the early pregnancy assessment clinic, and antenatal clinics.

Community midwives provide care for women and their babies both during the antenatal and postnatal period. They also provide a home birth service. As at November 2020, the trust reported an average homebirth rate of 4.42%.

From November 2019 and October 2020, there were 2,779 deliveries at the trust. This was similar to the number previously reported for the period April 2017 to March 2018, at 2,867 births.

We last inspected the maternity service at Bedford Hospital in August 2018. Bedford Hospital was registered as a different provider during this inspection. The service was rated as requires improvement overall; safe and well led were rated requires improvement, effective, caring and responsive were rated good.

During the 2018 inspection, we identified a number of concerns in the maternity service. As a result, requirement notices for breaches of regulation 12, 17 and 18 of the health and social care act (2014), were issued against the trust. The requirement notices informed the action the trust must comply with its legal obligation, and we requested an action plan from the trust, outlining steps that had to be taken to address the concerns we raised. The trust submitted an action plan following publication of the inspection report in December 2018.

Following 14 whistle-blower enquiries we had received between August and November 2020, and information we received from the trust, we carried out an unannounced focused inspection at Bedford Hospital on 5 November 2020.

Our findings

We visited clinical areas in the service including the delivery suite, Acorn suite, Orchard ward, the antenatal clinic, and the maternity day assessment unit. We spoke with 21 staff, including service leads, midwives, medical staff, maternity care support workers and student midwives. We reviewed 13 sets of patient records & six prescription charts and observed staff providing care and treatment to women.

Our inspection was unannounced (staff did not know we were coming) to enable us to observe routine activities. We carried out a focused inspection related to the concerns raised, this does not include all of our key lines of enquiry (KLOEs). As a result of this inspection we rated safe and well-led as inadequate, and effective as requires improvement. Overall the service was rated as inadequate.

Following this inspection, under Section 31 of the Health and Social Care Act 2008, we issued a letter of intent to the provider in respect to the regulated activity; Maternity and midwifery services. We took this urgent action as we believed a person would or may be exposed to the risk of harm if we had not done so. We also issued a notice of decision to put conditions on the trust's registration as we had significant concerns relating to staffing. In addition, we issued a section 29A warning notice to the trust as we found significant improvement was required in several areas. The section 29A warning notice gave the trust two months to rectify the significant improvements we identified. The trust took some immediate actions and developed an action plan to address the concerns raised.

Maternity

Inadequate ↓

Our rating of this location went down. We rated it as inadequate because:

- The service did not always have enough staff with the right qualifications, skills, training and experience to keep women safe from avoidable harm and to provide the right care and treatment. Staff often worked through breaks and missed training to make up for high levels of vacancies and staffing shortages. The service did not always make sure staff were competent for their roles. There were no staff competency assessments to ensure staff could interpret and make cardiotocography (technical means of recording the fetal heartbeat and the uterine contractions during pregnancy) classifications correctly. Consultant attendance when called for an emergency was not always immediate due to commitments within the gynaecology service. Managers did not always give agency staff and locum doctors a full induction.
- Risk to women was not always identified appropriately. There was not a formal triage centre or formal pathways of care for women who had been seen by the service with high risk symptoms. Staff did not always complete risk assessments for each women. Nationally recognised tools to identify women at risk of deterioration were not always used.
- The service did not always use the most up to date evidence-based guidance to inform the delivery of care and treatment. We found out of date policies which meant staff may not have been following the most up to date guidance. Mental health assessments were not always completed during a women's pregnancy.
- Leaders were aware of the challenges the service faced, however, timely action was not always taken to address the concerns identified within the service. Staff did not always feel respected, supported and valued. The service did not always have an open culture where staff could raise concerns without fear. Leaders did not always operate governance processes effectively to continually improve the quality of its services and safeguarding standards of care. We were not assured that incidents were always graded correctly according to the level of harm. Maternity performance measures were not displayed, which meant staff and the pubic were not informed of the outcomes and risks of the service. Timely action was not always taken to address concerns previously identified within the service.

However:

- There were processes in place to ensure equipment was checked daily. Staff managed clinical waste well. The service controlled infection risk well. Staff used equipment and control measures to protect women, themselves and others from infection. They kept equipment and the premises visibly clean. Staff understood how to protect women from abuse. Staff managed medicines well. The service used monitoring results to improve safety.

Is the service safe?

Inadequate ↓

Our rating of safe went down. We rated it as inadequate because:

Mandatory training

- The service provided mandatory training in key skills to all staff. However, not all staff were up to date with their training. The trust set a target of 90% for completion of mandatory training. The 90% target was met for one of the 10 mandatory training modules for which qualified midwifery staff were eligible, and one of the eight mandatory

training modules for which medical staff were eligible. Data provided by the service showed 72% of midwifery staff and 81% of medical obstetric staff had completed their basic life support training (BLS), and 41% of midwives had completed newborn life support training (NLS). Due to COVID-19, NLS courses were cancelled but training had resumed and plans were in place to rebook these. In addition to the trust's mandatory training, maternity staff attended a three-day multidisciplinary training course, which covered a PRactical Obstetric Multi-Professional Training (PROMPT) style 'skills and drills' training. As at 9 November 2020, 87% of maternity staff and 61% of obstetric medical staff had completed their PROMPT training. A trajectory had been compiled to demonstrate full compliance by end of December 2020. Anaesthetic and theatre teams were awaiting dates to be booked onto PROMPT in situ training sessions as training had expired in August 2019. As at 9 November 2020, data requested from the service showed 100% of obstetric medical staff had completed 'Gestation Related Optimal Weight (GROW) training, a recommendation from Saving Babies' Lives 2019. No data was received for the percentage of midwives trained in GROW. Data received following the inspection showed 73% of midwives and 63% of medical staff within maternity were compliant with CTG training.

- Training completion was monitored electronically, and staff received reminders to complete training. However, training compliance in most topics was low; therefore we were not assured that oversight was robust. Staff told us training was often cancelled due to low staffing levels. Staff also reported completing mandatory training in their own time due to clinical pressures. Training compliance was a concern identified at our last inspection.

Safeguarding

- Staff received training specific for their role on how to recognise and report abuse. The trust set a target of 90% for completion of safeguarding training. Maternity staff met the trust target of 90% for three of the four safeguarding modules. However, level 3 children's safeguarding training was significantly below the trust target at 77%. Low compliance with children's safeguarding training was a concern identified at our last inspection. Medical staff met the trust target of 90% for two of the four safeguarding modules. Level three children's safeguarding training was just below the trust target at 87%.
- During the inspection we raised concerns that the labour ward and Orchard ward posed a potential risk for baby abduction. During our inspection, we found anyone could exit the labour ward & Orchard ward. We observed visitors were required to be let into the ward through a secure door buzzer that staff operated. Babies did wear electronic tags, however, we observed staff, women and visitors leaving the labour ward and Orchard ward, without challenge, by pressing the exit button that did not require staff to operate. In addition, we asked three members of staff for the trust's baby abduction policy, but they could not locate it. Some staff were unaware of any baby abduction drills or scenario training, which meant staff may not know what to do in such circumstances. Data submitted by the trust on 11 November 2020 stated the last simulation of baby abduction was held 12 months ago. Simulations were held annually, and one was booked for 8 December 2020. The baby abduction policy was due for review in November 2019 and had not been updated. These concerns were raised with the trust following the inspection. Additional information provided detailed that some processes were in place to mitigate the risk for baby abduction. These included a baby tagging system with an anti-tamper mechanism, regularly tested tamper proof alarms at each end of the wards and CCTV. In addition, an action plan was submitted to review the current policy and provide staff with training. The trust told us they would undertake risk assessment for the access and exit point for labour ward and Orchard ward.
- Staff knew how to identify adults and children at risk of, or suffering significant harm and worked with other agencies to protect them. Staff knew how to make a safeguarding referral and who to inform if they had concerns. The trust had a named lead midwife for safeguarding who provided support, supervision, and updates to staff. Safeguarding policies and clinical pathways were in-date and were accessible to staff via the trust's intranet.

Cleanliness, infection control and hygiene

Maternity

- The service controlled infection risk well. Staff used equipment and control measures to protect women, themselves and others from infection. Staff followed infection control principles, including the use of personal protective equipment (PPE). The service followed current guidance for infection prevention and control when assessing and caring for women with possible or confirmed cases of COVID-19. Staff adhered to the trust's 'bare below the elbows' policy to enable effective hand washing and reduce the risk of spreading infections. Hand sanitising units and handwashing facilities were available throughout the unit and handwashing prompts were visible for staff, women and the public. Monthly infection prevention and control (IPC) audits were completed within the maternity service. The audits included, but were not limited to, hand hygiene compliance, equipment cleaning, and compliance with the tap flushing schedule (completed to prevent infection, such as legionella, from thriving). Data from September 2020 to October 2020 showed that all maternity areas scored 100% in the monthly hand hygiene audit. For the same period, maternity areas scored between 94-97% in their cleaning audits.
- Women were screened for Methicillin Resistant Staphylococcus Aureus (MRSA) in line with guidance. Where inpatient women had a known or suspected infection, they were cared for in single side rooms. There had been no cases of Clostridium difficile (C Diff) or MRSA bloodstream infections in the maternity service from November 2019 to October 2020.
- All areas were visibly clean and had suitable furnishings which were clean and well-maintained. Cleaning records were up-to-date and demonstrated that all areas were cleaned regularly. Housekeeping staff cleaned wards and public areas, in accordance with daily and weekly checklists. Staff cleaned equipment after patient contact and labelled equipment to show when it was last cleaned.

Environment and equipment

- The service had suitable premises and equipment to care for women and babies and keep them safe. The service had access to two obstetric theatres and a recovery area. The neonatal unit was close by if a baby's condition deteriorated and required an urgent transfer. The service had enough suitable equipment to help them to safely care for women and babies. We checked 26 items of equipment and saw that they had up to date safety testing, including resuscitaires, cardiotocography machines and weighing scales. There were processes in place to ensure equipment was checked daily. Staff carried out daily safety checks of specialist equipment. We reviewed daily checklists for the emergency equipment from 1 October to 5 November 2020 which were all completed.
- Staff managed clinical waste well. Staff disposed clinical waste safely. Waste management was handled appropriately with separate colour coded arrangements for general waste and clinical waste. Sharps, such as needles, were disposed of correctly in line with national guidance. Arrangements for control of substances hazardous to health (COSHH) were adhered to. Cleaning equipment was stored securely in locked cupboards.

Assessing and responding to risk

- Risk to women was not always identified appropriately. There was not a formal triage centre or formal pathways of care for women who had been seen by the service with high risk symptoms. The maternity day assessment unit had a designated four-bedded area located near the entrance of the Orchard ward. Women were seen for some symptoms on the labour ward and some women on the maternity day assessment unit. There were three telephone lines on the labour ward and one phone line on the day assessment unit to triage women over the phone. The same triage form was used on both the labour ward and assessment unit. However, there were no pathways of care to be followed for women triaged as low, medium or high risk. There was a risk women and babies would be exposed to harm as there was not a formal system in place to ensure they followed the appropriate pathway of care.
- We reviewed the telephone triage form and observed that information could be taken by a midwife, a student or a maternity care assistant (MCA). It was not appropriate for unqualified staff, such as students and MCAs, to triage

pregnant women. In addition, the service did not document or audit the time taken for a woman to be reviewed by a midwife and then by medical staff. Following feedback, the trust immediately removed MCAs and students from the triage form to ensure there was improved clarity as to who made the decision on where women were seen at triage. Senior leaders recognised triage pathways required streamlining. The trust submitted a plan following the inspection to include, allocating a midwife to manage the triage calls, developing documentation outlining formal pathways of care for those women accessing the service with antenatal complications, and an audit of compliance to review the time a woman waits to be seen by a midwife and a doctor (by March 2021). However, the improvement plan had not yet been embedded and we were not assured the time taken to complete the audit would mitigate the risk of potential harm to pregnant women.

- Nationally recognised tools to identify women at risk of deterioration were not always used. The maternity day assessment unit were not using nationally recognised tools, such as the 'Modified Early Obstetric Warning Score' (MEOWS) to identify women at risk of deterioration. The service did not adequately risk assess women in the antenatal unit as staff were not routinely completing MEOWS. Of the 10 MEOWS charts we reviewed overall on inspection on the labour ward and Orchard ward, only three were completed adequately. Therefore, women were at risk of not being identified if they were deteriorating and needed more frequent observations or immediate escalation to medical staff. The action plan submitted by the trust following the inspection included sending staff reminders in respect to use of MEOWS charts and compliance audits in November 2020. However, this had not yet been fully embedded and audited for compliance, therefore remained a risk.
- Swabs used for vaginal birth and perineal suturing were not always counted for completeness by two members of staff, in line with national recommendations (NSPA, reducing the risk of retained swabs after vaginal birth and perineal suturing: 1229 (May 2010). We reviewed 13 records and saw two members of staff had verified the swab count in 10 cases. In the remaining three records, we found gaps in the checks.
- During the inspection we attended and observed the 8am multi-disciplinary team (MDT) shift handover meeting and found handovers were not attended by all disciplines, there was no presence by an anaesthetist, theatre staff or staff from the neonatal unit. There were no formal structure, no introductions of staff, and no safety briefing. There was a risk that women would be exposed to the risk of harm as important information about risks, their care and treatment was not shared during handovers with all disciplines present. In accordance with *NHS Improvement- Implementing handovers and huddles: a framework for practice in maternity units March 2019* . The action plan submitted following the inspection included, implementation of a revised handover pack, aligned with national guidance best practice, regular monitoring of compliance with handover that will be undertaken through a spot check audit mechanism in February 2021. However, this had not yet been fully embedded and was not due for audit until February 2021.
- Staff mostly completed screening for specific issues. For example, carbon monoxide screening, which was part of 'saving babies lives 2016' initiative, was generally performed. Although this had been suspended since COVID-19, prior to this date of the 13 notes we reviewed, carbon monoxide was monitored as a minimum at booking in 11 cases (85%). This was an improvement since the last inspection.
- Staff completed booking risk assessments for each women at their initial booking appointment, which included social, medical and obstetric assessments. This enabled staff to decide if the women was a high or low risk pregnancy. We reviewed 10 maternity care records which confirmed these details.
- Staff mostly completed venous thromboembolism (VTE) assessments in line with service guidelines. VTE is a life-threatening condition where a blood clot forms in a vein. Of the 13 records reviewed, this was assessed in 11 cases (85%). Data received from the service following the inspection showed that for August 2020, September 2020 and October 2020, compliance with VTE assessments were 88%, 92% and 91% respectively.

Maternity

- Women with high-risk pregnancies, for example, due to a multiple pregnancy, diabetes, pre-eclampsia, and obstetric cholestasis, were regularly monitored and reviewed by an obstetrician. Women who were at high-risk of gestational diabetes were also referred for glucose tolerance testing.
- There was a pathway for the management of sepsis. Staff we spoke with described what actions they would take if a woman was admitted with suspected or known sepsis including the prompt use of the sepsis six tool, administration of fluids and antibiotics.
- The maternity service used an adapted version of the World Health Organisation's (WHO) surgical safety checklist. This was in accordance with national recommendations (NPSA 'Patient safety alert: WHO surgical safety checklist', January 2009). The checklist was used for women having a caesarean section or other surgical procedure relating to childbirth. We reviewed six WHO checklists during our inspection and found all but one were fully completed. Completion of the checklist was audited and from 7 October 2019 to 2 November 2020, the compliance rate for the completion of the checklist was at 100%. This meant the service could be assured that the team worked well together to keep women safe from avoidable harm.

Midwifery staffing

- The service did not always have enough maternity staff with the right qualifications, skills, training and experience to keep women and babies safe from avoidable harm and to provide the right care and treatment. At our last inspection in 2018, the maternity service had not fully reviewed their staffing levels and skill mix so that their levels were in line with the recommendations from their 'Birthrate Plus' review, which the trust received on 4 December 2017. This meant that the planned level of midwifery staff in each clinical area was not based on the trust's activity, case mix and demographics. The review indicated there was enough staff to provide a service for up to 3,000 births per year; however, the planned establishment for midwifery staffing in each clinical area was not correct. Birthrate Plus is recommended by the Department of Health, endorsed by the Royal College of Midwives (RCM), and incorporated within the standards issued by NHS Resolution. During this inspection, we found the staffing levels remained a significant concern. We had received 14 whistle-blower enquiries prior to the inspection between August and November 2020 and staffing issues was the main area of concern which staff told us about. We had concerns regarding staffing levels throughout the unit. We spoke to staff of all disciplines who raised concerns regarding safe staffing levels and felt that their views and comments regarding this were not being taken into account. Midwifery staff reported regularly missing breaks and working late due to low staffing levels. We were told by midwives and ward managers that actual staffing levels often did not meet planned staffing levels. Data submitted after the inspection indicated a number of unfilled shifts within the maternity unit. Between 5 October and 15 November there were a total of 175 unfilled shifts in the unit. This included 37 out of 42 early shifts with unfilled shifts, ranging from 1 to 4 midwives short and 25 out of 42 night shifts, ranging from 1 to 5 midwives short. Data reviewed prior to the inspection showed that during September 2020, 57 incidents were submitted regarding lack of suitably trained staff. We were also told that staff were often deployed to different areas to provide cover, leaving their designated areas without adequate staffing support.
- Information we received from whistle blowers prior to the inspection and staff we spoke to during the inspection told us the delivery suite coordinator was not always supernumerary. Information received prior to the inspection showed that between 22 September and 7 October 2020, out of 70 shifts, the band 7 midwives were supernumerary 63 times. There were six occasions where this was not possible. This meant that in the event that a high number of women attended the delivery suite, then they would be providing one to one care for a woman and not facilitating the communication between professionals and overseeing the risk and appropriate use of resources. This was not in line with the 'Safer Childbirth recommendations, October 2007, which states each delivery suite must have a rota of experienced senior midwives as delivery suite shift coordinators, supernumerary to the staffing numbers required for one-to-one care'.

Maternity

- Although midwifery staffing levels were regularly reviewed within the service, appropriate staffing levels were not always achieved and the service often relied on deploying staff from other areas to fill any shortfalls. Managers told us staffing levels and acuity of the service were reviewed four times a day. There was an escalation policy for staff to follow if staffing levels fell below agreed levels. This included the redeployment of midwives from other areas and/or specialist roles to support the unit when needed and ensuring bank and agency shifts were filled. Community midwives were also asked to support the unit when needed.
- The service had a high vacancy rate. The current vacancy rate was 14.64% as at 5 November 2020. This did not include sickness, maternity leave and staff redeployed. This was above the trust target of 5% and we were told on a number of occasions that the vacancy rate for midwives impacted on the ability of the unit to maintain staffing as planned. We asked the senior leadership team for these details; however they were not aware of them during our meeting with them. We were not assured that the senior leadership team knew what their staffing establishment was at the time of inspection.
- The service had a high turnover rate. The average turnover rate between April 2020 and September 2020 was 21%, against a trust target of 10-12%. In addition, the service had increasing sickness rates. The sickness rate from July to September 2020 were 3.84%, 5.03% and 6.4% respectively. This was above the trust target of less than 3.25%.
- Senior staff told us it had become apparent to the service during August 2020 that there were staffing issues in the labour, postnatal and antenatal wards. Consequently, the trust took the decision to pause the Continuity of Care (CoC) model and recall midwifery staff to work within the hospital. This resulted in the delivery suite staffing model returning to pre CoC levels. The trust had been undertaking a full review of staffing levels. This had shown that continued challenges were influenced by: a higher than average number of staff on maternity leave; the impact of COVID–19 whereby a number of staff were shielding, and clinical staff who could work, but were currently unable to undertake a patient facing role; sickness absence both long and short term, again impacted by COVID–19; a number of vacancies. The trust submitted an improvement plan following the inspection which included development and implementation of a recruitment strategy, redeployment of specialist midwives, use of enhanced bank rates to encourage improved fill rates and permission for the maternity unit to use high cost agency midwives to ensure safe staffing. However, we reviewed the rota for the forthcoming weeks which continued to have shifts unfilled, and were not assured that the service had sufficient numbers of staff in order to meet patient's needs and ensure they were being provided with safe care and treatment.

Medical staffing

- Medical staffing levels within the unit were generally sufficient. Consultant cover was from 8am to 7pm, Monday to Friday, with five hours cover spread over the weekend. However, the cover provided by consultants was not aligned to the labour ward alone. This included covering the gynaecology ward, gynaecology theatres, the emergency gynaecology clinic and taking calls from GP's out of hours and urgent and emergency care. Whilst on inspection, we were told of a recent example of a 20 minute delay to respond to a bleep to ask for consultant attendance on the labour ward. There was a risk that women would be exposed to the risk of harm if consultants were not readily available to attend an emergency on the delivery suite due to their commitments within the gynaecology service. Senior leaders told us this model was based on a "hot week" consultant and it was recognised that whilst the role was freed up from routine elective gynaecology work, there were other clinical demands on that post, for example, the acute gynaecology clinic. Following the inspection, the trust responded with immediate actions to increase consultant hours from 8am to 8.30pm and to a total of 12 hours over the weekend, equating to 74.5 hours of on-site cover. The service also increased the consultant workforce by appointing an additional locum consultant with plans to substantively recruit to that post. The trust was currently recruiting an additional senior middle grade (specialty doctor) to provide cover for emergency gynaecology afternoon clinics. However, this had not yet been fully embedded and audited for compliance, therefore there may still be a risk that women may be exposed to the risk of harm if consultants were not readily available, or there was a delay in obtaining a consultant in event of an emergency.

- Managers did not always give agency staff or locum medical staff a full induction before they started work. During the inspection we spoke to staff who confirmed agency maternity staff and locum doctors who were used for adhoc work, did not receive a trust induction. Staff told us this delayed some elements of care because the agency and locum staff did not have access to the trust guidelines, policies and computer systems. The trust submitted an action plan which included implementing a local induction pack and reminding staff of policy requirements related to local induction.

Records

- Staff kept records of women's care and treatment. However, records were not always clear, contemporaneous or filed in a chronological order. The maternity service used mostly paper-based records. Some electronic records, such as prescription charts, were also in use. Entries from antenatal appointments and current admissions were not always dated, timed or signed by staff.
- Women's records were not always stored securely on the maternity ward. Whilst we observed that women's records were stored in lockable trollies and filing cabinets next to the midwives' station, which were not always manned, we found that the trollies and cabinets were unlocked. Therefore, we were not assured that the service kept women's records secure at all times. This was a concern raised at our last inspection.

Medicines

- The service used systems and processes to safely prescribe, administer, record and store medicines. Medicines were stored securely in all clinical areas we visited. Controlled drugs (medicines subject to additional security measures) were stored correctly in locked cupboards and stock was checked by two qualified members of staff twice a day. Medicine storage areas were well organised and tidy, with effective processes in place to ensure stock was regularly rotated. All medicines we checked were within their use by date. Staff kept records of medicines fridge temperatures and ambient room temperature of their medicine rooms on the delivery suite and postnatal ward.
- The maternity service used an online prescribing and administration system for maternal prescriptions. We reviewed the medicine records for six women and found prescriptions were legible, named, dated, allergies and weight were clearly documented, and administration and route of administration were also clearly recorded. This was an improvement since our previous inspection where we found women's weight and any allergies were not always documented.
- Women at risk of developing a blood clot were prescribed anti-clotting medicine to reduce this risk, in line with national guidance (RCOG, Reducing the Risk of Venous Thromboembolism during Pregnancy and the Puerperium: Green-top Guideline No. 37a (April 2015).

Incidents

- Although staff recognised incidents, they did not always have time to report them. The trust used an electronic reporting system which all grades of staff had access to. Staff we spoke with knew what incidents to report and how to report them. However, due to clinical pressures, they did not always have enough time to complete the incident form. This posed a risk of harm if incidents had not been reported. Similar concerns were raised at the last inspection.
- In accordance with the Serious Incident Framework 2015, the trust reported seven serious incidents (SIs) in maternity which met the reporting criteria set by NHS England from August 2019 to September 2020.
- We reviewed incidents reported on NRLS by the trust from August to October 2020 which showed term babies admitted to the neonatal unit were graded as no or low harm. This meant that incorrectly graded incidents may not be investigated and there was a risk that women were not informed of the significance of harm caused to them or their baby, or that appropriate action was taken to prevent further occurrences. We were not assured that incidents

that were moderate, in line with definitions in Regulation 20 Duty of Candour guidance 2015, were always graded correctly according to the level of harm. The trust submitted an action plan following the inspection which included implementing the incident review process from their neighbouring hospital site to improve incident grading and ensure learning from incidents. However, this had not been fully embedded and incidents had been graded incorrectly which posed a significant risk.

- The trust had a duty of candour policy which staff could access through the trust's intranet. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain notifiable safety incidents and provide reasonable support to that person, under Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. A notifiable safety incident includes any incident that could result in, or appears to have resulted in, the death of the person using the service or severe, moderate or prolonged psychological harm. Staff we spoke with were aware of the importance of being open and honest with women and families when something went wrong, and of the need to offer an appropriate remedy or support to put matters right and explain the effects of what had happened. However, where incidents were not graded correctly there was a risk woman may not receive the correct response, duty of candour and support from staff.
- Lessons learned from incidents formed part of the 'Risky Business' newsletter, which was displayed and circulated to all the staff.

Safety Thermometer

- The service used monitoring results to improve safety. Staff used overarching national maternity indicators, as well as locally agreed standards, to provide oversight and assurance. Data submitted following the inspection stated the trust had stopped undertaking the point prevalence (safety thermometer) checklist in November 2018. The national requirement was halted in May 2020, within maternity services, as the data sample was small at the point of audit, the decision was taken to use the overarching national maternity safety indicators, supported by local safety and quality standards, to provide oversight and assurance. These indicators were scrutinised at monthly maternity clinical service quality meetings and provided assurance at the executive-led quality board and trust board quality committee. Immediate safety concerns would be highlighted through the daily safety huddles, incident management and professional escalation.

Is the service effective?

Requires Improvement 

Our rating of effective went down. We rated it as requires improvement because:

Evidence-based care and treatment

- The service did not always use current evidence-based guidance to inform the delivery of care and treatment. We found out of date policies which meant staff may not have been following the most up to date guidance. During our focused inspection, we found 20 polices that were out of date, some of which had been out of date since 2018 and were still accessible to staff. We also found 10 policies awaiting ratification and 11 standard operating procedures (SOPs) that were out of date. Out of date policies was an issue we found during the last inspection. The trust submitted an action plan following the inspection, which included reviewing the list of all outstanding policies, guidelines and procedures using a new template. However, there was no timeline for updating polices or a date for completing this.

- Mental health assessments were not always completed adequately. During our inspection, in 11 of the 13 notes we reviewed, mental health assessments were either not completed at all, or only partially completed using the nationally recommended 'whoolley' questions. This meant that women were at risk of not receiving appropriate care and referral if they were to develop a mental health condition during their pregnancy. The trust submitted an action plan following the inspection which included using safety briefings and service communication routes to ensure all staff were reminded of the need to consistently complete documentation related to mental health assessments, implementing standards and audits and to recruit a perinatal mental health midwife post. However, this had not yet been fully embedded and audited therefore remained a risk.

Patient outcomes

- Staff generally monitored the effectiveness of care and treatment. They used the findings to make improvements and mostly achieved good outcomes for women. The service maintained a maternity dashboard, which reported on birth activity, workforce, and obstetric and neonatal clinical outcomes. There were 32 performance measures detailed on the dashboard. The dashboard tracked monthly performance against locally agreed thresholds and national targets, where available. A traffic light system using red, amber, and green (RAG) ratings were used to flag most of the performance against agreed thresholds. A 'red flag' indicated areas that required action, to ensure safety and quality was maintained. Exceptions (red flags) reported on the maternity dashboard were reviewed monthly at the quality board meeting and the maternity clinical service quality meeting. The majority of red flags were in relation the number of successful vaginal births after caesarean (VBAC), serious incidents, and maternity sickness absence rates. The maternity service was an outlier for perinatal mortality in the 2019 MBRRACE report (deliveries January to December 2017). At which point, perinatal mortality was more than five percent higher than the UK average (much worse). As a result, the service undertook a perinatal mortality review. A number of recommendations were made and uploaded onto the national database. Actions were monitored through the maternity clinical service governance, and learning was disseminated through the risk and governance quarterly newsletter. The most recent 2020 MBRRACE report (deliveries January to December 2018) showed that the service had made improvements with regards to perinatal mortality and was no longer an outlier.
- Local audits were not always completed and actions taken to improve care and treatment. The maternity service had a local audit programme in place for 2020/21. However, none of the 53 audits listed on the plan had a proposed start or end date, and none of the audits were in progress or completed. Information relating to the current status of each audit was also not available. In addition, there were no recent examples of national audits which maternity services had been involved in.

Competent staff

- The service did not always make sure staff were competent for their roles. During the focused inspection, we identified concerns about cardiotocography (CTG) training and competency assessments. The service did not have appropriate systems in place to assess and monitor staff competency in relation to CTGs. Staff were required to complete annual 'K2 training', which was an online training systems for performing, reading and interpreting CTG outputs for women. However, there were no competency assessments at the end of the training. Data received following the inspection showed 73% of midwives and 63% of medical staff within maternity were compliant with CTG training. There was a risk staff were not trained and/or competent in interpreting and making CTG classifications correctly. Furthermore, the service did not have a fetal surveillance midwife in line with saving babies lives care bundle version two (2019) to support staff with CTG training and competencies.
- We raised our concerns around the adequacy of this training and lack of competency assessment with the senior leadership team. An action plan was submitted following our inspection which included implementing a programme of competency assessments to support CTG training for staff by December 2020. However, there was no deadline to

achieve full competency. Accordingly, we were not assured when all staff would be competent. Neither were we assured that mitigating measures were put in place pending all staff achieving full competency. This meant that service users would be exposed to the risk of harm if staff were permitted to interpret CTGs without assurance as to their competency, pending the introduction and completion of competency assessments.

- Compliance with annual appraisals for midwifery and medical staff in maternity were low. As at 11 November 2020, 44% of maternity hospital staff and 64% of obstetric medical staff at the trust received an appraisal against a trust target of 90%.

Multidisciplinary working

- Doctors, midwives and other healthcare professionals did not always work well together to benefit women and babies. Staff held regular multidisciplinary (MDT) meetings. However, we attended and observed the 8am MDT shift handover and found it was not attended by all disciplines of the multidisciplinary team. There was no presence by an anaesthetist, theatre staff or staff from the neonatal unit.
- Specialist midwives, such as the specialist diabetic midwife, were available to provide holistic care for women. However, staff told us specialist midwives were often deployed to work in other areas to provide cover, leaving their designated areas without adequate staffing support.

Is the service well-led?

Inadequate 

Our rating of well-led went down. We rated it as inadequate because:

Leadership

- Leaders were aware of the challenges the service faced, however, timely action was not always taken to address the concerns identified within the service. The maternity service was managed through the trust's maternity clinical service line. Following a recent merger, the services within the Bedford hospital site were under the leadership of a new executive director team. The merger had seen the implementation of new models of service delivery, and the leadership within the maternity service had seen a move to a clinically led model, accompanied with a change to the senior leadership team (SLT). The SLT comprised of an interim head of midwifery, a general manager and cross site clinical director. The trust had also recently appointed a substantive director of midwifery, due to commence in February 2021, working across both sites. An interim director of midwifery was in place based at the Bedford hospital site. The leadership triumvirate met on a weekly basis to discuss operational issues and mitigating actions. Additionally, on a monthly basis the triumvirate met with the clinical leads (consultants and matrons) to have wider conversations about operational delivery, staffing and agreed actions. These meetings were not formally minuted, however, leaders told us the outcomes of the discussions were fed into the formal quality and governance meetings. The leadership team had direct access to the trust board. The interim head of midwifery (HOM) was relatively new in post and met with the chief nurse on a weekly basis to discuss performance, operational capacity and concerns. The HOM had recently started to attend the performance meeting and quality committee. We saw that a maternity exception report (red flags) was presented at the trust's monthly quality board. Any concerns identified at this meeting were escalated to the trust's board meeting.
- We met with members of the SLT who demonstrated an awareness of the service's performance and the challenges they faced, including staffing issues and the longstanding poor culture, which had been present for numerous years.

However, we were not assured timely action was always taken to address the challenges and concerns identified within the service. We saw little action had been taken to address some of the concerns raised at our last inspection in 2018. Whilst some actions and change processes had taken place to improve some of the challenges the service faced, these were still in their infancy and yet to be fully embedded.

- During our inspection, we met with the senior leadership team who were unable to tell us the unfilled shift rate and were not clear on the maternity unit's staffing establishment. Therefore, we were not assured senior leaders had full oversight of staffing, in order to deal with concerns raised by staff regarding low staffing levels. Furthermore, we were not assured that there was appropriate governance to identify unfilled shifts, escalate such matters and put in place mitigations to deal with these unfilled shifts in order to provide safe care and treatment.

Vision and Strategy

- The service had a vision for what it wanted to achieve developed with all relevant stakeholders. The vision was focused on sustainability of services and aligned to local plans within the wider health economy. It focussed on providing safe, high quality, sustainable care for all. The vision of the service was "to deliver to everyone the excellent safe service we expect for ourselves". Their mission was to "deliver excellence through safe patient centred care supporting a positive experience for women, children and their families and our workforce". The vision had been developed with involvement from staff and linked to delivering the trust's values. We saw the vision was publicly displayed throughout the maternity unit. Staff we spoke with were committed to providing safe care and improving the patient experience. The service worked collaboratively with neighbouring trusts, clinical commissioning groups, other stakeholders, and service users to establish a local maternity system (LMS), in response to national recommendations.

Culture

- Staff did not always feel respected, supported and valued. The service did not always have an open culture where staff could raise concerns without fear. All staff we met during our inspection were welcoming, friendly and helpful. However, staff were very aware of the longstanding poor culture and staffing concerns. They expressed to us the impact the longstanding staffing issues and poor culture had impacted on staff morale. Staff we spoke with were visibly upset. Staff told us that some of the senior midwives were difficult to approach and there was a blame culture within the service. Staff morale was very low. All staff we spoke with raised concerns regarding safe staffing and felt that their views and comments regarding this were not being taken into account. Staff reported continually escalating concerns relating to staffing levels with no response.
- During the focused inspection both staff and maternity SLT told us the poor culture had been present for a number of years. Following the inspection, senior leaders told us the trust had been working to strengthen support for staff in the unit as low morale across all staff groups was evident. Following the merger, the trust executive had, in response to issues including culture, put in place new service line clinical leadership with the appointment of a cross-site clinical director, a new interim head of midwifery and recruited to a new director of midwifery post, with an interim candidate in post ahead of the start date of the substantive candidate. The trust's director of organisational development (OD) and chief nurse had supported the unit through a range of regular listening events. Additionally, a maternity specific OD plan has been developed with dedicated OD staff resource to support delivery. A previous initiative around "Energetic Workforce", which was stalled pre-merger and due to COVID-19 pressures, was being refreshed and reviewed. This was complemented by a consultant specific development programme and the allocated funding had been targeted to provide particular support to new consultant appointees. Furthermore, the trust

recently took an opportunity to secure some medium term support to strengthen pastoral and personal support to maternity staff. However, whilst steps had been taken to address cultural issues and a new maternity SLT were in place, actions to improve the long-term history of poor culture and morale were in their infancy and not yet fully embedded or effective.

- All NHS trusts are required to nominate a freedom to speak up guardian (FTSUG). The role of the FTSUG supported staff who wished to speak up about a concern or issue and ensured that any issue raised was listened to and the feedback was provided to them on any actions or inactions because of them raising an issue. In the last four months, between August and November 2020, the FTSUG service had received seven enquiries in relation to the maternity service. Concerns raised were in relation to maternity staffing levels and lack of support.

Governance

- Whilst governance processes were in place, leaders did not always operate these effectively to continually improve the quality of its services and safeguarding standards of care. The maternity governance structure replicated the triumvirate model across the trust. Led by the general manager, supported by a clinical lead and head of midwifery, the unit reported through the operational quality board to the quality committee as a sub-committee of the trust board. The head of midwifery had direct access to the board through the quality committee. Risk and quality governance was reviewed on a monthly basis through quality groups and daily safety huddles which took place with the management team and matrons.
- During our focused inspection, we found that whilst governance processes were in place, these were not fully effective. There remained a lack of oversight from the senior leadership and executive team. A number of the issues identified during our focused inspection were pre-existing issues that had already been highlighted at the 2018 inspection. Requirement notices were issued in relation to these breaches of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The trust developed an action plan in response to these breaches, and submitted regular updates, however, we found at our focused inspections some of the concerns were still present. The systems and processes that were in place to address the concerns from 2018 had not been fully embedded within the service. We found concerns relating to the governance processes of incident grading and appropriate review, as well as concerns around out of date policies. This indicated current governance processes were not effective.
- The service held monthly clinical governance meetings. We requested minutes of the last three meetings and were provided with the minutes from June 2020, July 2020 and August 2020. The minutes showed that the head of midwifery and risk management midwife were present at most of these meetings. We reviewed the meeting minutes which confirmed governance matters such as incidents, risks, performance, guidelines, audits and patient experience were discussed. The maternity service held joint monthly perinatal morbidity and mortality meetings with the children's service. We observed good multidisciplinary attendance at the meeting held in August and September 2020.

Management of risk, issues and performance

- Leaders and teams used systems to manage performance. They identified and escalated relevant risks and issues and identified actions to reduce their impact. The service had a senior matron leading risk and quality governance with daily oversight on incidents and risk issues. Any incidents that were graded as moderate and severe harm would be reviewed, escalated where necessary and a review and timeline undertaken. A risk register was used to identify and manage risks to the service. The risk register contained 27 risks and included a description of each risk, alongside mitigating actions, and assurances in place. An assessment of the likelihood of the risk materialising, its possible impact and the review date were also included.

Maternity

- Maternity performance measures were reported through the maternity dashboard, with red, amber, green ratings to enable staff to identify metrics that were better or worse than expected. However, the dashboard was not displayed in clinical areas, this meant that staff and the public were not informed of the outcomes and risks of the maternity service.

Information Management

- During our inspection, we saw the arrangements in place to ensure confidentiality of maternity patient records was not always robust. We found the trollies and filing cabinets where patient records were stored, were unlocked. This was a concern raised at our last inspection.
- The service collected reliable data and analysed it. Data or notifications were submitted to external organisations as required. The maternity service had clear performance measures and key performance indicators (KPIs), which were effectively monitored. These included the maternity dashboard and clinical area KPIs. The maternity dashboard parameters were presented in a format to enable it to be used to challenge and drive forward changes to practice. The parameters had been set in agreement with local and national thresholds, which allowed the service to benchmark themselves against other NHS acute trusts. The service submitted data to external bodies as required, such as the National Neonatal Audit Programme and MBRRACE-UK. This enabled the service to benchmark performance against other providers and national outcomes.

Engagement

- Systems in place to engage with staff were not always effective. Staff told us team meetings did not take place regularly or they were unable to attend due to clinical pressures and short staffing. Staff told us they did not always feel they were kept informed and consulted about changes to the service provision, they did not always feel their views were listened to or acted upon.
- Leaders engaged with women, the public and local organisations to plan and manage services. They collaborated with partner organisations to help improve services for women. The service took account the views of women through the Maternity Voices Partnership (MVP). At our last inspection, there was no MVP in place. However, during the focused inspection we found this was in place. Senior leaders told us monthly meetings took place and the service were very interactive. There were collaborative relationships with external partners and stakeholders to build a shared understanding of challenges within maternity and the needs of the local population, and delivery of services to meet those needs. The service was working collaboratively with service users, neighbouring trusts, and commissioners via the LMS, to ensure national recommendations for maternity care were implemented across the region.

Learning, continuous improvement and innovation

- Timely action was not always taken to address concerns previously identified within the service. We found concerns during this inspection which we had previously highlighted to the service at our last inspection in 2018. This included, but was not limited to, concerns with staffing levels, concerns regarding the poor culture amongst staff within the service, and low training compliance. We were not assured timely action was always taken to continuously improve and address the challenges and concerns identified within the service.
- Leaders did not always encourage participation in research. The service was not involved in any research projects at the time of our inspection.

Maternity

Areas for improvement

Action the trust MUST take is necessary to comply with its legal obligations.

- The service must ensure there are enough midwifery staff to deliver safe care and treatment. (Regulation 18 (1)).
- The service must ensure staff complete mandatory, safeguarding and any additional role specific training in line with the trust target. (Regulation 18 (2) (a)).
- The service must ensure there is a formal triage centre and formal pathways of care for women seen with high risk symptoms/problems. (Regulation 12 (2) (a)).
- The service must ensure the maternity day assessment unit is using nationally recognised tools to identify women at risk of deterioration. (Regulation 12 (2) (a)).
- The service must ensure the delivery suite coordinator is always supernumerary. (Regulation 12 (2) (b)).
- The service must ensure consultants are present and can respond to requests from labour ward in a timely manner. (Regulation 12 (1)).
- The service must ensure agency midwives and locum doctors receive an adequate induction prior to commencing duties. (Regulation 18 (2) (a)).
- The services must ensure mental health assessment using the 'whoolley' questions are completed adequately. (Regulation 12 (2) (a)).
- The service must ensure access and exit points to the unit are safe to reduce the risk of baby abduction. (Regulation 12 (2) (b)).
- The service must ensure there is a robust system in place to assess and grade incidents correctly. (Regulation 12 (2) (b)).
- The service must ensure multidisciplinary team working is improved and all disciplines attend MDT handover meetings. (Regulation 12 (2) (b)).
- The service must ensure staff receive an annual appraisal in line with the trust target. (Regulation 18 (2) (a)).
- The service must ensure policies and guidance are reviewed in a timely manner. (Regulation 12 (2) (b)).
- The service must ensure there is a system in place to assess staff competencies following completion of CTG training. (Regulation 12 (2) (c)).
- The service must ensure that all records are kept securely. (Regulation 17 (2) (c)).
- The service must improve the culture and ensure it supports the delivery of high quality sustainable care, where staff are actively encouraged to raise concerns and clinicians are engaged and encouraged to collaborate in improving the quality of care. (Regulation 12 (1)(2i)).

Action the trust SHOULD take to comply with a minor breach that did not justify regulatory action, to prevent it failing to comply with legal requirements in future, or to improve the quality of services;

- The service should consider recruiting a fetal surveillance midwife in line with saving babies lives care bundle version two (2019).
- The service should consider displaying safety information.

Maternity

Enforcement

Under Section 31 of the Health and Social Care Act 2008, we issued a letter of intent to the provider in respect to the regulated activity; Maternity and midwifery services. We took this urgent action as we believed a person would or may be exposed to the risk of harm if we had not done so. We also issued a notice of decision to put conditions on the trust's registration as we had significant concerns relating to staffing.

In addition, we issued a section 29A warning notice to the trust as we found significant improvement was required in several areas. The section 29A warning notice gave the trust two months to rectify the significant improvements we identified.